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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,599	01/03/2007	Anke Gasche	1209.003	5413

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ROGITZ & ASSOCIATES
750 B STREET
SUITE 3120
SAN DIEGO, CA 92101

EXAMINER	
CRONIN, ASHLEY L	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
06/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,599	GASCHE, ANKE	
	Examiner	Art Unit	
	ASHLEY CRONIN	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *17 and 26-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment filed on April 5, 2010. Claims 1, 16, and 18-19 have been amended and claim 17 has been cancelled. Claim 16 has been amended to overcome the objection made in the previous office action; therefore, the claim objection has been withdrawn. A new set of drawings has been filed to overcome the objection to the drawings; therefore, the drawings objection has been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1- 3, 5- 6, 11, 14-16, 18-21, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Griego et al. (US Pub. No. 2002/0095168 A1).

4. Regarding claims 1 and 18-21, McClellan et al. discloses a kit capable of performing an inversion of a tubular anatomical structure (column 2, lines 9-13), said kit comprising: a tube 21 (Fig. 11) extending between a proximal end and a distal end 40 (Fig. 11), said tube 21 defining at least one inner channel (Fig. 11), said distal end 40 being adapted to be inserted into a vessel of a patient (in this case a fallopian tube, however, this prior art may be used in other tubular anatomical structures - abstract), an elongated flexible element 44 (Fig. 11) extending between a proximal end and a distal

end 43 (Fig. 11) said elongated flexible element 44 being adapted for passing through said inner channel (passes through tube 21; Fig. 11), means 51 (Fig. 11) disposed near said distal end 43 of said elongated flexible element 44 (Fig. 12) for anchoring said distal end of said elongated flexible element 44 to at least one of said interior walls of the tubular anatomical structure (column 8, lines 15-26) when said distal end 43 is disposed within the central lumen of the tubular structure 30 (Fig. 11), such that pulling said elongated flexible element 44 backward provides force for inverting said structure (Figs. 11-13); and means 40, 41 for providing counterforce against said anatomical structure base 31 (Fig. 11) is adapted for being advanced over said elongated flexible element 44 toward said structure base 31 and engaging with said structure base 31 (Figs. 11-13; column 7, line 45 - column 8, line 48). McClellan fails to teach a cutting device for enlarging an orifice of said central lumen of said appendix; wherein said cutting device comprises a sphincterotome; wherein said cutting device comprises a needle knife; wherein said cutting means comprises an elongated wire forming a wire loop at a distal end, said wire being electrically conductive.

However, Griego et al. teaches an endoscopic catheter (Fig. 1) comprising a distally located tissue cutting device wherein the cutting device may be a sphincterotome, a papillotome (wire loop), or a needle knife and the cutting device may operate in response to energy from an rf heating source (paragraph [0016]; electrically conductive – papillotome), in order to cut anatomical tissue that is to be treated endoscopically (paragraph [0019]).

The use of McClellan's surgical device (which can be used with other tubular anatomical structures - abstract) for performing an appendectomie is considered proper and is common in the art of similar surgical devices, such as the device taught by McGuckin, Jr. (US Pat. No. 5,868,760). McGuckin, Jr. teaches an apparatus that is in one case used for Fallopian tubes sterilization while also having applicability to performing appendectomies where cutting is implemented (column 9, lines 28-40). The addition of the cutting element, as taught by Griego et al., to the device of McClellan would not teach away from the device's intended use since the device is not only used in Fallopian tubes but is also used in other anatomical structures.

Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify McClellan et al.'s device to include a cutting device for enlarging an orifice of said central lumen of said appendix; wherein said cutting device comprises a sphincterotome; wherein said cutting device comprises a needle knife; wherein said cutting means comprises an elongated wire forming a wire loop at a distal end, said wire being electrically conductive, as suggested and taught by Griego et al., for the purpose of cutting anatomical tissue that is to be treated endoscopically.

5. Regarding claims 2-3, 5-6, 11, 14-16, and 25, McClellan et al. further discloses wherein said elongated flexible element 44 is an elongated flexible catheter (column 5, lines 53-56); further comprising a guiding means for guiding said distal end 43 of said elongated flexible element 44 into said central lumen 30 of said tubular structure (column 7, lines 63-67); wherein said means (balloon 51) disposed at said distal end 43 of said elongated flexible element 44 comprises at least one balloon 51 attached to said distal end 43 of said elongated flexible element 44 (column 8, lines 15-26), and wherein said elongated flexible element 44 defines a first inner channel 50 (Fig. 11) in connection with an interior area 52 of at least one balloon 51 for inflating and deflating said at least one balloon 51 (Figs. 11-13; column 8, lines 15-37); wherein said at least one balloon 51 has an outer surface carrying a skid resistant structure 54a, 54b, etc. (barbs - column 8, lines 19-31); wherein said means 40, 41 for providing counterforce comprises an elongated flexible tubular element 40 (Fig. 4) extending between a proximal end and a distal end, said tubular element 40 defining at least one inner channel 45 (Figs. 4-5), said at least one inner channel 45 comprising a first inner channel 45 (capable of receiving a scope - receives catheter 44, and is capable of receiving a scope; Fig. 3); further comprising a ligating means 41 (Figs. 3 and 11-13) being positionable near said tubular structure base 31 for ligating said structure when inverted (Figs. 12-13; column 4, lines 17-36); wherein said ligating means 41 comprises a loop at a distal end 40 (column 4, lines 25-26); wherein said loop 41 is detachable (column 8, lines 38-48); and wherein said means 40, 41 for providing counterforce against the base 31 of the structure comprises a ring 41 (“loop” – column 4, lines 25-

26), wherein said ring 41 is adapted for being advanced over said elongated flexible element 44 toward said base 31 and engaging with said base 31 (Figs. 11-13; column 8, lines 38-48).

6. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Griego et al. (US Pub. No. 2002/0095168 A1) further in view of Trauthen et al. (US Pat. No. 5,263,928).

7. Regarding claims 4 and 10, McClellan et al. as modified above with Griego et al suggests the limitations of claims 1 and 3 above, but does not teach the guiding means having a wire guide, and wherein said elongated flexible element is a catheter disposed over said wire guide; further comprising a catheter being positionable within an inner channel of a colonoscope for irrigating said central lumen of said appendix.

However, Trauthen et al. teaches a catheter 20 (Fig. 1) and endoscope 26 (Fig. 1) assembly comprising a guiding means consisting of a wire guide 82 (Fig. 1), wherein said wire guide 82 is disposed within said catheter 20 (at distal tip 30; Fig. 1; column 3, lines 24-54), and wherein the catheter 20 is capable of irrigation (via bundle 24 and irrigation duct 46 – column 4, lines 55-59; Fig. 1), in order to observe, diagnose, and treat body cavities (column 1, lines 7-14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify McClellan et al.'s device such that said guiding means comprises a wire guide, and wherein said elongated flexible element is a catheter disposed over said wire guide; further comprising a catheter being positionable within an inner channel of a colonoscope for irrigating said central lumen of said

appendix, as suggested and taught by Trauthen et al., for the purpose of observing, diagnosing, and treating body cavities.

8. Claims 7- 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Griego et al. (US Pub. No. 2002/0095168 A1) further in view of Slepian (US Pat. No. 5,328,471).

9. Regarding claims 7-8, McClellan et al and Greigo et al combination fail to teach the elongated flexible element (catheter) defines a second inner channel, said second inner channel having at least one distal opening at the distal end of the elongated element; wherein said at least one balloon comprises a plurality of balloons connect by said first inner channel, and wherein said elongated flexible element defines a second inner channel which includes at least one opening located between any two adjacent balloons.

However, Slepian teaches a balloon catheter assembly 100 (elongated flexible element; Fig. 1b) comprising a first inner channel 152 (Fig. 1b) and a second inner channel 156 (Fig. 1b), a plurality of balloons 150, 151 (Fig. 1b) connected by said first inner channel 152 and wherein the second inner channel 156 includes at least one opening located between any two adjacent balloons 150, 151 (Fig. 1b), in order to deliver a therapeutic agent through the opening to the procedure site (column 5, lines 39-43).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify McClellan et al.'s device to include a second inner channel, said second inner channel having at least one distal opening at

the distal end of the elongated element; wherein said at least one balloon comprises a plurality of balloons connect by said first inner channel, and wherein said elongated flexible element defines a second inner channel which includes at least one opening located between any two adjacent balloons, as suggested and taught by Slepian, for the purpose of delivering a therapeutic agent through the opening to the procedure site.

10. Claims 9, 13, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Griego et al. (US Pub. No. 2002/0095168 A1) further in view of Frassica et al. (US Pat. No. 5,483,951).

11. Regarding claims 9, 13, and 24, McClellan et al. as modified discloses all claimed elements ***except for*** wherein said first inner channel is coated with a lubricious material; and further comprising a colonoscope.

However, Frassica et al. teaches an endoscope assembly (colonoscope - column 1, lines 11-20) comprising a suction channel with a lubricious inner tube forming a lubricious inner lumen (abstract), in order to provide an anti-friction surface for the air and water to pass through (column 9, lines 28-33).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify McClellan et al.'s device such that the first inner channel is coated with a lubricious material, as suggested and taught by Frassica et al., for the purpose of providing an anti-friction surface for the air and water to pass through.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Griego et al. (US Pub. No. 2002/0095168 A1) further in view of Altman et al. (US Pat. No. 4,464,175).

13. Regarding claim 12, McClellan et al and Griego et al combination fail to disclose the tubular element further comprises a circular seal disposed within said first inner channel at or near said proximal end of said tubular element, and wherein when a colonoscope is disposed within said first inner channel, said circular seal engages with said colonoscope and seals a region between said colonoscope and said tubular element.

However, Altman et al. teaches a surgical device comprising an outer tube 30 (Fig. 1) wherein the outer tube 30 has a circular diaphragm 25 (Fig. 1) mounted on a cap 22 to provide a seal, wherein the diaphragm has a small opening permitting the passage of an endoscope (column 3, lines 40-48), in order to preserving an air-tight system (column 3, lines 46-48).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify McClellan et al.'s device such that said tubular element further comprises a circular seal disposed within said first inner channel at or near said proximal end of said tubular element, and wherein when a colonoscope is disposed within said first inner channel, said circular seal engages with said colonoscope and seals a region between said colonoscope and said tubular element, as suggested and taught by Altman et al., for the purpose of preserving an air-tight system.

14. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClellan et al. (US Pat. No. 6,736,822 B2) in view of Griego et al. (US Pub. No. 2002/0095168 A1) further in view of Redha (US Pat. No. 5,282,813).

15. Regarding claims 22-23, McClellan et al. as modified discloses all claimed elements ***except for*** wherein said means disposed at said distal end of said elongated flexible element for anchoring comprises at least one flap disposed at said distal end, said at least one flap being adjustable between a closed and an open position; wherein said elongated element comprises a catheter defining a central lumen and an inner elongated element slidingly received within said central lumen, said inner elongated element defining at least one depression, and wherein said at least one flap comprises a knob extending into said central lumen, said depression engaging with said knob, wherein said at least one flap are adjusted between said closed position and said opened position by operating said inner elongated element.

However, Redha teaches an apparatus delivered and retrieved with a catheter (column 7, lines 37-45) comprising at least one flap 13, 33 (Fig. 2) wherein the flap 13, 33 is adjustable between a closed and opened position (Fig. 1 to Fig. 2) further comprising an inner elongated element 14 (Fig. 1) slidingly received within a central lumen of the device, said inner elongated element 14 defining at least one depression 11 (depression lies where element 24 of structure 11 hits; Fig. 1), and wherein said at least one flap 13, 33 comprises a knob (notch on flaps 13, 33 - Fig. 2) extending into said lumen, said depression 11, 24 engaging with said knob (Fig. 2), wherein said at least one flap 13, 33 are adjusted between said closed and open position by operating

said inner elongated element 14 (Fig. 1 to Fig. 2; column 5, line 58 – column 6, line 7), in order to expand the flaps of the assembly during a surgical procedure (column 6, lines 3-7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify McClellan et al.'s device such that said means disposed at said distal end of said elongated flexible element for anchoring comprises at least one flap disposed at said distal end, said at least one flap being adjustable between a closed and an open position; wherein said elongated element comprises a catheter defining a central lumen and an inner elongated element slidingly received within said central lumen, said inner elongated element defining at least one depression, and wherein said at least one flap comprises a knob extending into said central lumen, said depression engaging with said knob, wherein said at least one flap are adjusted between said closed position and said opened position by operating said inner elongated element, as suggested and taught by Redha, for the purpose of expanding the flaps of the assembly during a surgical procedure.

Response to Arguments

16. Applicant's arguments filed April 5, 2010 have been fully considered but they are not persuasive.

Examiner disagrees with the applicant that the combination of the cutting device as taught by Griego and the device as taught by McClellan would ruin the intended use of McClellan's device. As addressed above in the rejection, examiner would like to point out that it has been held that a recitation with respect to the manner in which a claimed

apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). Furthermore, McClellan et al. do not limit the use of their device to merely Fallopian tubes; as stated in the abstract, the device can be used in other tubular anatomical structures.

McGuckin, Jr. (US Pat. No. 5,868,760) teaches a surgical device that can be used in Fallopian tubes for sterilization, while also having applicability to invert an appendix and cut the tissue therein. Examiner believes that this reference along with the intended use clause, it would be proper to add the cutting element to McClellan's kit in order to cut the anatomical tissue when used in other procedures besides the explicitly disclosed Fallopian tube sterilization.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ASHLEY CRONIN whose telephone number is (571)270-7899. The examiner can normally be reached on monday-friday, 8am-5pm est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. C./
Examiner, Art Unit 3731
June 18, 2010

/Gary Jackson/
Supervisory Patent Examiner
TC 3700
June 20, 2010